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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,539	05/02/2005	Katsuya Togawa	M&M-079-USA-PCT	1593

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,539	TOGAWA ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-5,9,10 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8,11-15 and 17* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 6 – 8, 11 – 15 and 17 in the reply filed on December 12, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims.1 – 5, 9, 10, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Drawings

The drawings are objected to because:

1) Figure 2 displays the reference number **6** two times, which does not appear to be correct.

2) The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

On pages 17-18 of the specification, the reference numbers "cylindrical member **9**," "ring-shaped member **8**," "smaller diameter portion **9b**," "step **9a**," upper end **2b**," and "larger diameter portion **9c**" are disclosed with respect to Figure 2, however these reference numbers are not displayed in Figure 2.

3) The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Figure 10 displays the reference numbers **63a**, **67**, **68** and **68a**, however, these reference numbers are not disclosed in the specification.

Figure 11 displays the reference numbers **74**, **74a**, **76**, **77**, **78**, and **83c**, however, these reference numbers are not disclosed in the specification.

4) The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "**A**" has been used to designate both "blood" and "a first internal space" (see Figures 5, 8, 10 and 11; p24, line 24; and p29-31).

5) The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "**63**" has been used to designate both "cylindrical member" and "male screw" (see p27, lines 11-22).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

On page 19, line 8, "the opening" is disclosed as reference number "**3a**," however "the opening" was previously and subsequently disclosed as reference number "**2a**."

Appropriate correction is required.

Claim Objections

Claim 8 is objected to because of the following informalities:

Claim 8 appears to be missing the term "the" prior to the terms "mean fiber diameter" and "filled density."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 12 – 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the phrase " a third filter member ... is provided in **precedent stage**," which is vague and indefinite because it is unclear where exactly the third filter member is contained. The term "precedent stage" relates more to a method claim, rather than a device claim; therefore, it is unclear how exactly the filter members are positioned.

Claims 12 and 13 recite the term "the internal space," which lacks antecedent basis and is also vague and indefinite, because it is unclear where exactly the "anticoagulant component" and the "accelerator" are stored within the filter apparatus. Are the "anticoagulant component" and the "accelerator" merely floating somewhere inside the apparatus or are they contained within or on top of one of the various filter members?

Claim 14 recites the terms "the blood accommodation part" and "the second filter member," which both lack antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 – 8, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitajima et al. (US 5,876,605).

Kitajima et al. teach a filter unit 1 (apparatus) comprising:

a first filter member 10 through which plasma can move faster than coruscles; and

a microporous (plasma or serum separating) membrane 13 having a pore size of about 0.3 to 5 μm (Applicant's membrane claims 1-3), serially connected in a subsequent stage with the first filter member (see Figure 1; column 1, lines 58-64; column 2, lines 45-62; column 5, lines 46-52; column 6, lines 10-27; column 9, lines 14-20; and Example 1).

With respect to Applicant's claim 7, the filter member serves as the first filter member 10 or 11, the microporous membrane 13 serves as a second filter member, and a third filter member 10 made of fiber having a mean fiber diameter of not less than 3.0 μm and a bulk density of about 0.02 to 0.3 g/cm^3 is provided in a precedent stage of the first filter member 10 or 11 (see Figure 1; column 5, lines 46-52; column 6, lines 1-27; and Example 1).

With respect to Applicant's claim 8, the first filter member 10 is made of fiber, has a mean fiber diameter from 0.2 to 3.0 μm and a filled density from 0.02 to 0.3 g/cm^3 (see Figure 1; column 5, lines 46-62; and column 6, lines 1-4; and Example 1).

With respect to Applicant's claim 14, an aqueous solution is added to the blood sample prior to filtering the sample through the first and second filter members, wherein the solution has an osmotic pressure that prevents the rupturing of blood cells, particularly erythrocytes, or the puncturing of blood cell membranes (see column 3, lines 6-67; column 4, lines 1-49; and column 5, lines 22-52). Although Kitajima et al. fail to teach the specific range of the osmotic pressure for the aqueous solution as being 200 to 300 mOsm/kg, Applicant's specification discloses that the aqueous solution has an osmotic pressure of 200 to 350 mOsm/kg, which is the osmotic pressure which prevents the breakage of erythrocytes (see Applicant's specification p36). Therefore, the aqueous solution of Kitajima et al. would inherently have an osmotic pressure within Applicant's range because Kitajima et al.'s aqueous solution is also taught to contain an osmotic pressure that prevents the rupturing of blood cells, particularly erythrocytes, or the puncturing of blood cell membranes.

With respect to Applicant's claim 15, the aqueous solution can contain an HL agent (internal substance) (see column 3, lines 6-67; column 4, lines 1-59; and column 5, lines 22-52).

Claims 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazawa et al. (US 6,045,699).

Yazawa et al. teach a filter apparatus comprising:

a glass fiber filter 32 (first filter member) through which plasma can move faster than corpuscles; and

a microporous membrane 33 (plasma or serum separating membrane) having a pore size of about 0.3 to 5 μm (Applicant's membrane claims 1-3), serially connected in a subsequent stage with the glass fiber filter (see Figure 2; column 2, lines 16-67; column 3, lines 1-52; column 4, lines 56-67; column 5, lines 1-10 and 52-54; column 7, lines 26-28 and 64-67; column 8, lines 1-29; and Example 1).

With respect to Applicant's claim 8, the glass fiber filter 32 is made of fiber, has a mean fiber diameter less than 10 μm, wherein the retaining particle size is about 0.6 μm or more, and a filled density from 0.05 to 0.13 g/cm^3 (see Figure 2; and column 3, lines 20-52).

Claims 6 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (US 5,423,989).

Allen et al. teach a filter device 10 (apparatus) comprising:

a first filter member 14 through which plasma can move faster than corpuscles; and

a finer (plasma or serum separating) membrane 18 having a pore size of about 0.2 to 7 μm (Applicant's membrane claims 1-3), serially connected in a subsequent stage with the first filter member (see Figure 1; column 1, lines 65-68; column 2, lines 1-46; column 3, lines 28-40 and lines 66-68; and column 4, lines 1-46).

With respect to Applicant's claim 17, the filter device contains a strip of an immunochromatographic receiving element 22 (diagnostic agent) to which the plasma or serum is added to (see Figure 1; column 4, lines 30-46; and column 6, lines 9-18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Ayres (US 3,891,553).

The Kitajima et al. reference, which was discussed in the first 102(b) rejection above, fails to teach that the first filter member has a property of absorbing fibrinogen contained in blood, plasma, or a fibrinogen solution.

Ayres teaches a serum and plasma separator comprising a container, a piston, and a filter means, wherein the filter means comprises a first filter member which will

pass red blood corpuscles therethrough but will not pass fibrin and fibrous constituents of blood, and a second filter member which will pass the light phase of blood but which will not pass red blood corpuscles therethrough. Therefore, the first filter member is characterized to have pore sizes which allow for the passage of red blood cells, but will not allow the passage of particulate material, such as fibrin. Thus, the first filter member removes particles of fibrin and other particulate matter from an applied blood sample (see column 2, lines 3-39; and column 4, lines 2-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide with the first filter member of Kitajima et al. the property of absorbing fibrinogen as taught by Ayres because Ayres teaches the benefit of including a first filter member in a plasma or serum separating device that is characterized to have pore sizes which allow for the passage of red blood cells, but will not allow the passage of particulate material, such as fibrin, in order to effectively remove particles of fibrin and other particulate matter from an applied blood sample prior to the removal of red blood cells from the sample.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Bell (US 2003/0206828).

Kitajima et al. further fail to teach that an anticoagulant compound is stored in at least a part of the internal space of the filter apparatus.

Bell teaches a whole blood sampling device comprising a tube having a self-filling capability and that includes a blood separation filter. The filter has a plurality of

pores sized to permit passage of selected blood constituents, such as blood plasma, through the device. The tube can include an anti-coagulant reagent, preferably in dry form, dispensed throughout the interior of the tube, which prevents the clotting of blood contained within the tube, and further facilitates the flow of blood plasma from the tube through the filter (see Abstract; and paragraph [0012]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter unit of Kitajima et al. an anticoagulant component as taught by Bell because Bell teaches the benefit of including an anti-coagulant reagent in the interior of a blood sampling device in order to prevent the clotting of blood contained within the device, and further to facilitate the flow of blood plasma through a filter contained within the device.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Anraku (US 5,413,786).

Kitajima et al. fail to teach that an accelerator for accelerating coagulation of blood is stored in at least a part of the internal space.

Anraku teaches a method for accelerating blood coagulation by contacting blood with an accelerator comprising a metal complex. The addition of an accelerator for blood coagulation to a blood sample is beneficial because it gives a good separation effect between the serum and the blood clot, which allows for the separation of the serum from the blood clot in a high yield and without causing a change in the serum, so

that the serum can be used for every kind of biochemical and clinical test (see Abstract; and column 3, lines 49-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter unit of Kitajima et al. an accelerator for accelerating coagulation of blood as taught by Anraku because Anraku teaches the benefit of adding an accelerator for blood coagulation to a blood sample because it gives a good separation effect between the serum and the blood clot, which allows for the separation of the serum from the blood clot in a high yield and without causing a change in the serum, so that the serum can be used for every kind of biochemical and clinical test.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Chu (US 6,632,681).

Kitajima et al. fail to teach that the filter unit contains or stores a strip of immunochromatographical diagnostic agent to be added to the separated plasma or serum.

Chu teaches a device and method for filtering a biological derived sample, such as blood, wherein the device includes a container, a filter, and a fluid flow-through matrix. The filter is used to retain debris in the liquid that would otherwise interfere with an assay for the biological sample. The matrix is used to retain a reagent that interacts in some way with the biological sample. A subsequent reaction surface is utilized with the device and method, wherein the reaction surface contains an immobilized capture

reagent (strip of immunochromatographical diagnostic agent) that interacts with the filtered sample, such as through an immunoassay for a sample analyte (see Abstract; column 2, lines 17-24; column 3, lines 2-41; and column 5, lines 9-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter unit of Kitajima et al. a reaction surface containing an immobilized capture reagent (strip of immunochromatographical diagnostic agent) as taught by Chu because Chu teaches the benefit of including a reaction surface containing an immobilized capture reagent with a device and method for filtering a biological sample in order to receive and interact with the filtered sample, and to allow for the subsequent immunoassay of a desired sample analyte.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Ohmura et al. (US 6,139,757).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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